

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

ATTY.'S DOCKET: LEVY=18A

In re Application of:	)	Art Unit:
	)	
Joseph LEVY et al	)	Examiner:
	)	
Appln. No.: Not Yet Assigned	)	Washington, D.C.
	)	
Filed: Even Date Herewith	)	April 16, 2004
	)	
For: COMPOSITIONS FOR	)	Confirmation No.:
PREVENTING HORMONE	)	
INDUCED ADVERSE EFFECTS	)	

**INFORMATION DISCLOSURE STATEMENT [IDS]**

Honorable Commissioner of Patents and Trademarks  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir :

This Information Disclosure Statement is submitted in accordance with 37 CFR §§1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

[X] 1. This IDS should be considered, in accordance with 37 CFR §1.97, as it is filed within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.

[X] 2. In accordance with 37 CFR §1.98, this IDS includes a list (e.g., form PTO/SB/08A) of all patents, publications, or other information submitted for consideration

by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached.

*(check boxes A and/or B and fill in blanks, if appropriate)*

☐ A. Document(s) \_\_\_\_\_ is (are) deemed substantially cumulative to document(s) \_\_\_\_\_, and, in accordance with §1.98(c), only a copy of each of the latter documents is enclosed.

☐ B. Certain documents were previously cited by or submitted to the Office in the following prior application(s), which are relied upon under 35 U.S.C. 120:

*(insert serial numbers and filing dates of prior applications)*

Applicant(s) identifies these documents by attaching hereto copies of the forms PTO-892 and PTO-1449 from the files of the prior application(s) or a fresh PTO/SB/08A listing these documents, and request that they be considered and made of record in accordance with §1.98(d). Per 37 CFR §1.98(d), copies of these documents need not be filed in this application.

☒ C. Document AK-AR are U.S. patent(s) and/or published application(s). As this is a U.S. application filed after June 30, 2003, or an entry into national stage under 35 USC §371 after June 30, 2003, the requirement to file copies of such U.S. patents or published applications has been waived. (Office of Patent Legal Administration - Pre O.G. Notice of July 11, 2003).

☒ 3. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).

4. In accordance with 37 CFR §§1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information


In re of Continuation Appln.

cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant(s) reserves the right to prove that the date of publication is in fact different.

Respectfully submitted,

BROWDY AND NEIMARK  
Attorneys for Applicant(s)

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 4

**Complete if Known**

Application Number	Not Yet Assigned
Filing Date	Even Date Herewith
First Named Inventor	Joseph LEVY et al
Group Art Unit	
Examiner Name	
Attorney Docket Number	LEVY=18A

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	AK	US-5,475,006 A	12-12-1995	BURTON et al	
	AL	US-5,516,528 A	05-14-1996	HUGHES et al	
	AM	US-5,827,900 A	10-27-1998	LEVY et al	
	AN	US-5,830,887 A	11-03-1998	KELLY	
	AO	US-5,834,044 A	11-10-1998	SCHMITZ et al	
	AP	US-5,904,924 A	05-18-1999	GAYNOR et al	
	AQ	US-6,132,790 A	10-17-2000	SCHILIPALIUS	
	AR	US-6,218,436 B1	04-17-2001	HOWARD et al	
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**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				

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Sheet 2 of 4	Attorney Docket Number	LEVY =18A	

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	AS	ACADEMY HEALTH. Carotenoid Complex x 30- Quest. [retrieved on 2003-1-02]. Retrieved from Internet <URL:http://www.ishop.co.uk/ishop/934/shopscri32.html>	
	AT	ADLERCREUTZ, et al, "Plasma Concentrations of Phyto-Oestrogens in Japanese Men". (13 Nov. 1993). Lancet. 342(8881):1209-10. Abstract.	
	AU	BAIL et al, "Estrogenic And Antiproliferative Activities On MCF-7 Human Breast Cancer Cells By Flavonoids". (14 Aug 1998). Cancer Letters. 130(1-2):209-216. Abstract.	
	AV	CHAN, et al, "Plasma Insulin-Like Growth Factor-I And Prostate Cancer Risk: A Prospective Study". (23 Jan. 1998). Science. 279:563-566.	
	AW	CONSTANINOU, et al, "Genistein Induces Maturation Of Cultured Human Breast Cancer Cells And Prevents Tumor Growth In Nude Mice <sup>1-3n</sup> ". (1998). Am J Clin Nutr. 68(suppl):1426S-30S.	
	AX	ERNSTER, et al, "Benefits and Risks of Menopausal Estrogen and/or Progestin Hormone Use". (Mar. 1988). Prev Med. 17(2):201-23. Abstract.	
	AY	FREUDENHEIM, Jo. et al, "Premenopausal Breast Cancer Risk and Intake of Vegetables, Fruits, and Related Nutrients", JOURNAL OF THE NATIONAL CANCER INSTITUTE, vol. 88, no. 6, March 20, 1996. pp. 340-348.	
	AZ	GOODERHAM, et al, "A Soy Protein Isolate Rich In Genistein And Daidzein And Its Effects On Plasma Isoflavone Concentrations, Platelet Aggregation, Blood Lipids And Fatty Acid Composition Of Plasma Phospholipid In Normal Men". (Aug. 1996). J Nutr. 126(8):2000-6. Abstract.	
	BA	HANKINSON, et al, "Circulating Concentrations Of Insulin-Like Growth Factor I And Risk Of Breast Cancer". (9 May 1998) Lancet. 351(9113):1393-1396. Abstract.	
	BB	HEALTHY ORIGINS®. Lyc-O-Mato Natural Tomato Lycopene. Product Brochure. [[retrieved on 2003-Jan-02]. Retrieved from Internet <URL:http://w3www.healthyorigns.com/lycomato.htm>	
	BC	KARAS, et al, "Lycopene interferes with cell cycle progression and insulin-like growth factor I signaling in Mammary Cancer Cells". (Jan. 2000). Nutrition and Cancer. 36(1):101-111. Abstract.	
	BD	KING, R., "A Discussion Of The Role Of Oestrogen And Progestin In Human Mammary Carcinogenesis". (Nov. 1991). The Journal of Steroid Biochemistry and Molecular Biology. 39(5): 811-818. Abstract.	

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	BE	Le ROITH, et al, "Molecular and cellular aspects of the insulin-like growth factor I Receptor". Apr. 1995). Endocrine Reviews. 16(2):143-163.	
	BF	LOBO, R., "The Role of Progestins in Hormone Replacement Therapy". (Jun. 1992). AM J Obstet Gynecol. 166(6 Pt 2):1997-2004. Abstract.	
	BG	LUTEIN INFORMATION BUREAU, Protective Breast Cancer Effect From Carotene And Lutein/Zeaxanthin. 1996. Electronic LUTEIN STUDIES AND BREAST CANCER. [online], [retrieved on 2003-Jan-02]. Retrieved from the Internet <URL:http://www.luteinfo.com>	
	BH	NISHINO, H., "Cancer Prevention by Carotenoids". (18 Jun 1998). Mutat Res. 402(1-2):159-163. Abstract.	
	BI	OMENN, et al, "Effects of a combination of beta carotene and vitamin a on lung cancer and cardiovascular disease". (2 May 1996). The new England journal of Medicine. 334(18):1150-1155.	
	BJ	PETO, et al, "Can Dietary Beta-carotene Materially Reduce Human Cancer Rates?". (19 Mar. 1981). Nature. 290(5803):201-8. Abstract.	
	BK	SIGHTINGS. Soy Phytoestrogens- They Can Actually Promote Cancer. 12-7-1999. [online]. [Retrieved on 2003-Jan-02]. Retrieved from the Internet ,URL:http://www.sightings.com>	
	BL	SINGH, Diljeet and Scott Lippman, "Cancer Chemoprevention Part 1: Retinoids and Carotenoids and Other Classic Antioxidants", ONCOLOGY, vol. 12, no. 11, November 1998, [25 pp.]	
	BM	STAFFA, et al, "Progestins and Breast Cancer: An Epidemiologic Review". (Mar. 1992). Fertil Steril. 57(3):473-491. Abstract.	
	BN	TANAKA, et al, "Chemoprevention Of Rat Oral Carcinogenesis By Naturally Occurring Xanthophylls, Astaxanthin And Canthaxanthin". (1995). Cancer Research. 55(18):4059-4064. Abstract.	
	BO	TANAKA, et al, "Suppression Of Azoxymethane-Induced Rat Colon Carcinogenesis By Dietary Administration Of Naturally Occurring Xanthophylls Astaxanthin And Canthaxanthin During The Postinitiation Phase". (1995). Carcinogenesis. 16(12):2957-2963. Abstract.	
	BP	UNITED STATES DEPARTMENT OF AGRICULTURE RESEARCH SERVICE. ARS NATIONAL PROGRAMS. National Program Annual Report: FY 1998. [online]. [retrieved on Jan. 9, 2003]. Retrieved from Internet <URL:http://nps.ars.usda.gov/documents/_doc.htm?npnumber=107&docid=231&cg_id=26...>	

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**First Named Inventor**

Joseph LEVY et al

**Group Art Unit**

Examiner Name

Sheet 4

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Attorney Docket Number

LEVY=18A

Examiner  
Initials\*Cite  
No. <sup>1</sup>

Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published

 $T^2$ 

**BQ**

WILSON, Jean. "Hormones and Hormone Action", HARRISON'S PRINCIPLES OF INTERNAL MEDICINE. 1991 part 12: Endocrinology and Metabolism, 12<sup>th</sup> Edition. pp. 1647-1652.

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	AF	KLEINMAN, Dita et al "Modulation of Insulin-like Growth Factor I (IGF-I) Receptors and Membrane-Associated IGF-binding Proteins in Endometrial Cancer Cells by Estradiol" ENDOCRINOLOGY Vol 136, No. 6, 1995, PP. 2531-2537.	
	AG	KLOTZ, Diane et al., "Activation of a Uterine Insulin-like Growth Factor I Signaling Pathway by Clinical and Environmental Estrogens: Requirement of Estrogen Receptor- $\alpha$ " ENDOCRINOLOGY, vol. 141, No. 9 September 2000, pp. 3430-3439.	
	AH	SHARONI et al, "Anticarcinogenic Properties of Lycopene" SPECIAL PUBLICATION- ROYAL SOCIETY OF CHEMISTRY, vol 181, 1996, pp. 378-385.	
	AI	VanEENWYK et al, "Dietary and Serum Carotenoids and Cervical Intraepithelial Neoplasia" INTERNATIONAL JOURNAL OF CANCER, vol. 48, no. 1, 1991, pp. 34-38.	
	AJ	WANG et al, "Phytoestrogen Concentration Determines Effects on DNA Synthesis in Human Breast cancer Cells", NUTRITION AND CANCER, vol. 28, no. 3, 1997, pp. 236-247.	

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